K131299
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510K Summary of safety and effectiveness

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This summary of 510(K) safety and effectiveness information is submitted in accordance with the requirements of 21 CFR Part 807.92

1. GENERAL INFORMATION

·Establishment:	Beijing Crealife Technology Co., Ltd.
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Date of Preparation of Summary:	Jan. 16, 2013
Device Name:	
·Trade Name:	Anythink® / Anythink PACS Workstation
·Classification:	Picture Archiving and Communication System
Classification Panel:	Radiology
CRF Section:	21 CFR§892.2050
·Device Class:	Class II
·Product Code:	LLZ

2. SAFETY AND EFFECTIVENESS INFORMATION SUPPORTING THE SUBSTANTIAL EQUIVALENCE DETERMINATION

·Intended Use:

The Anythink® is a medical image processing system, which offers comprehensive solutions to viewing, manipulation, communication and storage of multi-modality DICOM images and data on exchange media.

The Anythink® is a universal imaging platform, and supports different modalities, but it is not intended for the displaying of digital mammography images for diagnosis in the U.S.

·Device Description

The Anythink® is based on Windows XP, providing a set of software solutions with flexible configurations in accordance with different medical imaging missions and demands. The system accepts multi-modality DICOM images and allows for view, post-processing, and communication. This product is not intended for use with or for the primary diagnostic interpretation of mammography images in the U.S.

Due to specific customer requirements and the clinical focus, the Anythink® consists of two parts: Basic Functions and Optional Functions.

Basic functions are mandatory, allowing view, easy manipulation, storage and communication of DICOM formatted images, except in the case of mammography images. Management of patient information is also included.

Optional Functions are a set of professional image processing functions, designed for specific modalities. Depending on the precise requirement, customers can select the appropriate function(s) from the optional functions, under the precondition of installing Basic Functions.

The clinician retains the ultimate responsibility for making the pertinent diagnosis

based on their standard practices. The Anythink® is intended to assist the physician in diagnosis or treatment planning.

·Technological characteristics

The Anythink® will be marketed as a software solution for the end user (with recommended hardware requirements). It will be installed by Crealife's service engineers. The Anythink® described supports DICOM formatted images, and the system is based on the Windows XP operating system.

· General Safety and effectiveness concerns

The Anythink® software is specified, validated and tested under a registered ISO13485 and 21 CFR Part820 compliant Quality System.

The device labeling contains instructions for use and any necessary cautions and warnings, to provide for safe and effective use of the device.

Risk Management is ensured via a Risk Analysis, which is used to identify potential hazards. These potential hazards are controlled via software development, verification and validation testing.

· Substantial Equivalence

The Anythink®, addressed in this premarket notification, is substantially equivalent to the following commercially available devices:

510K Number	Trade or Model Name	Manufacturer
K072728	Syngo Multimodality Workplace	Siemens AG Medical Solutions

Technological characteristics comparison of the Anythink and predicate devices

Anythink		SIEMENS Syngo-Multimodality Workplace	
Function	Description	Function	Description
Hardware requirement	CPU: Dual-core 2.8G Hard disk: 250G Memory: 4 GB Monitor Driver: 19 inch LCD The resolution is no less than 1280*1024 Video card: Nvidia serial video card, 1G video memory CD Drive: DVD-RW Input Device: Keyboard/Mouse 100M/1000M network card	Hardware requirement	Type: FSC Celsius R640 Processor: 2 x 3.0 GHz Intel Xeon Dual core RAM: 4 GB (upgradable to 12 GB) System disk: 73 GB Hard disk for image data: 147 GB DVD writer: DVD-R, CD-R DVD reader: DVD-ROM, CD-ROM Floppy disk: 3,5", 1,4 MB Graphics card: OpenGL graphics Network: 2 x Gigabit Ethernet LAN on board Monitors: Flat-screen color monitor, high end 19" and/or Flat screen monochrome monitor, high end
Operating system	Microsoft Windows XP	Operating system	Windows XP
Patient information management	Provides creating new, editing and deleting patient information and other management functions, inquires and ranks patient information using key words; provides disk backup function and burns data to DICOM, AVI or MPEG format. Applicable for medical images from DICOM compliant sources, except digital mammography.	syngo Patient Browser	Offers consistent access to patient and exam data from all applications.
		Archiving and Networking	DICOM Media Storage for data exchange on CD and DVD media.

Anythink		SIEMENS Syngo-Multimodality Workplace	
Function	Description	Function	Description
Image Browsing	Supports adjusting windows width/level by hotkeys, presetting tools or manually; single/multiple window display, switching images within one series as well as among different series. Image switching between various patients is also available. Applicable for medical images from DICOM compliant sources, except digital mammography, can apply to image adjustment of different human tissue, body position, to meet the requirements of reading images.	syngo Viewing	Offers comprehensive functions for 2D processing and image evaluation. Multimodality display with a wide range of intuitive tools. Display and arrange the images in the way best suited to the diagnostic task. Review, process and evaluate the results and prepare them for supporting physician's diagnosis. Send the images to *syngo* Filming, store them, or send them to other locations in the hospital.
Image Manipulation	Provides converting positive-negative image, local/overall zoom, dying scheme, image flip (vertical/horizontal), image rotate (+/- 90 degree); image edge enhancement/ smoothing, image measurement and annotation. Applicable for medical images from DICOM compliant sources, except digital mammography.		
Image Transmit	Supports image transformation between the system and other DICOM devices and can input images from disk to system; Applicable for medical images from DICOM compliant sources, except digital mammography.	Archiving and Networking	syngo offers DICOM functions such as receiving and sending digital examinations and local data exchange to media like CD-R or DVD as well as connecting the syngo MultiModality Workplace to the radiological network..

Anythink		SIEMENS Syngo-Multimodality Workplace	
Function	Description	Function	Description
Image Storage	Provides six image/series storage function, allows saving current image to temporary area/clipboard/file/database, saving current image sequence as video file or back to database. Applicable for medical images from DICOM compliant sources, except digital mammography. /		DICOM Storage for data transfer and archiving to connected network nodes DICOM Storage Commitment to confirm successful storage at destination DICOM Query & Retrieve to search and access patient data on connected DICOM nodes DICOM Print for documentation of images on DICOM-capable laser cameras and network printers
3D reconstruction (3D View)	Multiplanar Reconstruction MPR: Applicable for CT or MRI image, used for the 3D displaying of various tissue ;	syngo 3D Basic	Processes volume datasets from various modalities as MIP, MPR, or SSD reformats, quickly and easily in routine use.
	Max/Min Intensity projection MIP: Applicable for CT or MRI image, mainly used for 3D displaying of bone, angiosteosis and other high density tissue;		
	Shaded surface Display: Applicable for CT or MRI image, used for 3D display of bone, lung and other tissues;		
	Volume Rendering: Applicable for CT or MRI image, used for 3D display of various tissue;	syngo 3D VRT	Displays CT, MR, NM, and conventional angiography volume datasets with excellent quality to the finest detail and provides advanced editing and provides advanced editing, including bone removal. Volume Rendering Technique: 3D visualization of volume data.
	Virtual Endoscopy: Applicable for CT or MRI image, used for 3D display internal wall of vessel and cavity.	Syngo Fly Through	Multi-modality application for CT, MR and 3D-XA data. Provides virtual endoluminal views of hollow structures

Anythink		SIEMENS Syngo-Multimodality Workplace	
Function	Description	Function	Description
	Edit 3D: Applicable for observing, selecting, measuring and annotating of 3D images		
XA heart and coronary artery analysis	Quantitative Coronary artery analysis(QCA): Applicable for XA coronary artery projection image, mainly used for vessel stenosis analysis, calculating stenosis rate and other relevant parameters; Functional implementation method: defined analyze-needed vessel, segmentalize vessel outline, calculate reference vessel outline, calculate stenosis analysis parameter, carry on multiple stenosis analysis; this implementation process applies Live-wire algorithm. The function is under the precondition of installing Basic Functions.	syngo Angio (DSA)	syngo Angio (DSA) Shifts DSA image processing of native and subtracted angiography series to the syngo MultiModality Workplace – the imaging system is freed immediately for the next acquisition. • syngo QCA Provides quantitative coronary vessel analysis, optimized for small vessels like coronary arteries.

Anythink		SIEMENS Syngo-Multimodality Workplace	
Function	Description	Function	Description
	Left Ventricular functional Analysis(LVA): Applicable for XA heart projection image, mainly used for the analysis of the cardiac ejection functional and wall motion; Function implementation method: select end-diastolic image, define the left ventricular outline of end-diastolic; select end-systole image, define the left ventricular outline of end-systole; input patient's height, weight; calculate ejection fraction and other heart functional parameters; select wall movement analysis method (radial line method, center line method) The function is under the precondition of installing Basic Functions.		• syngo LVA Provides left ventricle analysis including e. g. ejection fraction calculation and wall motion analysis. • syngo LVA biplane Provides left ventricle analysis for simultaneous biplane acquisitions. • syngo QVA Provides quantitative vessel analysis for abdominal and peripheral vessels.

Anythink		SIEMENS Syngo-Multimodality Workplace	
Function	Description	Function	Description
CT coronary artery analysis	Applicable for CT image, mainly used for analyzing coronary artery; Implementation method: extracting and adjusting coronary artery tree in the CTA image, define single coronary artery vessel and vessel analysis in the 3D image. This function applies QCA calculation method. The function is under the precondition of installing both Basic Functions and 3D View.	syngo Circulation	syngo Circulation Offers comprehensive cardiac and chest pain evaluation with integrated reporting in a single application. • syngo Circulation QCA with Plaque Analysis Allows fast coronary tree segmentation, accurate stenosis quantification, stent planning and plaque analysis. • syngo Circulation LVA Enables complete ventricular function evaluation in multiphase cardiac datasets.
CT Colon Analysis	Applicable for CT image, an assistant tool to obtain the endoluminal view of the colon derived for the purpose to detect colonic lesions. It provides functionality for extracting colon image, endoluminal display of the colon, and marking suspected lesions.) Implementation method: 3D panoramic view, unfolding colon and endoscope of extracting colon, analysis colon, display colon in the CTC image. Apply the VR+SSD. The function is under the precondition of installing both Basic Functions and 3D View.	syngo Colonography	syngo Colonography Locates and evaluates colon polyps using non-invasive, real-time virtual 3D endoluminal viewing for CT datasets. • syngo Colonography Polyp Enhanced Viewing (PEV) Supports as automated second reader tool the visualization of lesions. • syngo Colonography Unfolding Allows the user to unfold the colon for easier polyp visualization and navigation.

Anythink		SIEMENS Syngo-Multimodality Workplace	
Function	Description	Function	Description
CV-3D	Creates 3D models of coronary vessel segments with two projection images, providing image analysis and stent indications of 3D angiostenosis. Applicable for XA projection image, mainly used for 3D quantitative analysis of vessel. Implementation method: select two vessel projection image of which the angle is between 60 and 120 degree, separately define perfusion vessel's stenosis information, stenosis vessel 3D display, stenosis parameter calculation, virtual stent display; This function is under the precondition of installing Basic Functions	syngo IC3D	syngo IC3D Creates 3D models of coronary vessel segments for highly accurate quantification of lesions – stent size and length quantification with as few as two projection images.

· Conclusion as to Substantial Equivalence

The Anythink®, described in this premarket notification has the same intended use and similar technical characteristics as the device listed above.

In summary, the Anythink® does not introduce new indications for use, nor does the use of the device result in any new potential safety risks. The Anythink® is substantially equivalent to and performs as well as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 22, 2013

Beijing Crealife Technology Co., Ltd.
% Mr. Ned Devine
Senior Staff Engineer
Underwriters Laboratories, Inc.
333 Pfingsten Road
NORTHBROOK IL 60062

Re: K131299
Trade/Device Name: Anythink PACS Workstation
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: April 16, 2013
Received: May 07, 2013

Dear Mr. Devine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Michael D. O'Hara for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K131299

Device Name: Anythink PACS Workstation

Indications for Use:

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The Anythink® is a universal imaging platform, and supports different modalities, but it is not intended for the displaying of digital mammography images for diagnosis in the U.S.

Prescription Use X AND/OR Over-the-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(Please do not write below this line - continue on another page if needed)

Concurrence of the CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Michael D. O'Hara

(Division Sign-Off)

Office of In Vitro Diagnostics and Radiological Health

510(k) Number K131299